



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR INFECTIOUS DISEASES
SELECT AGENT PROGRAM
ATLANTA, GEORGIA

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
NATIONAL CENTER FOR IMPORT-EXPORT
PRODUCTS PROGRAM
RIVERDALE, MARYLAND



Memorandum

Date: February 24, 2003

From: Acting Director,
Select Agent Program

Associate Deputy Administrator
National Animal Health Policy and Programs

Subject: Registration applications for Select Biological Agents and Toxins

To: Responsible Official (RO)

ATTENTION: APPLICATIONS DUE MARCH 12, 2003

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* required the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) to establish requirements regarding possession, use, and transfer of select biological agents and toxins. The new requirements were published on December 13, 2002, in the Federal Register by HHS (42 C.F.R. Part 73) and by USDA (7 C.F.R. Part 331 and 9 C.F.R. Part 121).

Your laboratory facility or entity indicated that it possessed select biological agents and toxins. In order for your entity to lawfully possess select biological agents and toxins after either February 7 and 11, 2003 (the effective dates for HHS and USDA regulations, respectively), you must accomplish the following:

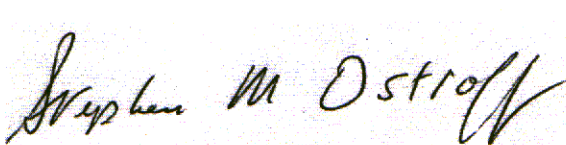
- **All entities must file an application by March 12, 2003 under the new rule, regardless of current registration status unless they meet exclusion criteria.** The application should be sent to the appropriate agency, which is determined by the type of select biological agent or toxin possessed by your entity.
- **Entities that declared possession of a select biological agent or toxin that determine they are exempt under the provisions indicated in HHS (42 C.F.R. Part 73.6) and by USDA (7 C.F.R. Part 331.4 and 9 C.F.R. Part 121.4-5), are not required to register.** However, exempt entities, or entities that reported possession but have since destroyed or transferred the agent, are requested to submit a letter to the appropriate agency as indicated below and provide details regarding why they are exempt or no longer possess a select biological agent or toxin.

- **For select biological agents and toxins covered by HHS, the Responsible Official must file an application with CDC's Select Agent Program** (Address: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Rd NE, Mailstop E-79, Atlanta, Georgia 30333). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov/od/sap>. The new application form is posted on the Select Agent Program website (<http://www.cdc.gov/od/sap>). It is also available on request via telephone (1-888-274-1757) or FAX (1-404-325-2667). Help with questions or concerns related to completing forms is also available at these numbers.

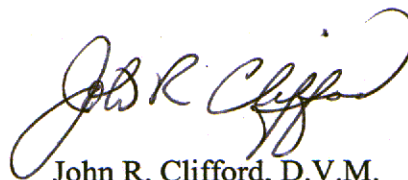
For select biological agents and toxins covered by USDA, the Responsible Official must file an application with APHIS (Address: National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 40, Riverdale, MD 20737-1231, telephone: 301-734-3277; facsimile: 301-734-3652). A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The new application form is posted on the APHIS website at the above address. Help with questions or concerns related to completing forms is also available at these numbers.

- **For HHS/USDA overlap agents, the Responsible Official can file an application with either CDC or APHIS.**
- **Enclosed with this letter are shipping labels to facilitate sending your application package to CDC or APHIS.** When registering for overlap agents, the RO may choose to use either the CDC or APHIS label. Please do not send the application to both agencies.
- **All transfers of HHS or USDA select biological agents and toxins after March 12, 2003 must be pre-authorized by CDC or APHIS, respectively.** Requests to transfer overlap agents may be submitted to either agency but will be pre-authorized by both agencies prior to transfer. The new EA-101 form (available on the Web sites reflected above) must be directed to the appropriate agency *prior* to transfer.

Your cooperation and assistance in this effort to improve safety and security for the possession, use, and transfer of select biological agents and toxins in the United States is greatly appreciated.



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